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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,137	Applicant(s) HAUCK, DOUGLAS J.	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 23-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Election of Species Requirement

Applicant's election of the ultimate species "veneers", "glazes" and "flavorings" in the reply filed on 11-3-05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-18 and 23-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The following information is critical or essential to the practice of the invention, but not is not included in the claim(s) and is not enabled by the disclosure:

- 1) the temperatures used for "low-firing" the claimed glazing mixtures; and
- 2) the materials used to make the glazing mixtures.

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In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976), is viewed as applicable precedent in this particular fact situation. In that case, achieving a desired alloy coating required special processing conditions, including using a temperature “higher than what is ordinarily considered optimum.” *Mayhew* at 358. Those special conditions were “practicable” only because a “special cooling apparatus, specially located” was employed. *Id.* The court found that because the use of a cooling zone, specially located, was essential to producing the claimed alloy coatings, claims not specifically reciting the use of such a cooling zone were not adequately supported by the disclosure. *Id.*

In the instant case, it is difficult to see how a glaze can be “low-fired” at temperatures which would not destroy any pharmaceutical, therapeutic agent, or flavoring agent incorporated therein. See for example USP 4,431,451, a typical prior art document which discloses methods for glazing crowns. As demonstrated therein, the term “glazing composition” is generally understood to refer to ceramic compositions, and the temperatures used for “low-firing” are “low” only in a relative sense. See specifically col. 8, lines 31-44, wherein the term “low-firing” is defined as “generally below 960 degrees Celsius”. Indeed, the temperatures used are too high to avoid thermal decomposition even of certain minerals such as mica (col. 7, lines 36-40), let alone temperature-sensitive organic compounds such as drugs and flavoring agents.

Applicant’s disclosure does in fact actually provide less guidance than the disclosure at issue in *Mayhew*. Applicant has provided no guidance whatsoever concerning special conditions and/or materials which might permit the processing of

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temperature-sensitive drugs and flavoring agents under typical ceramic firing conditions. Applicant's working example 2 (paragraph [0038]) is likewise uninformative, merely stating that an unspecified "medication" is infused into an unspecified "final glaze", using "standard dental techniques".

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) The term "low-firing" in claim 19 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not in fact provide any guidance whatsoever, as discussed in the "Written Description" rejection supra.

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2) Claim 21, third line, the scope of the phrase “compositions to improve oral health” is unclear. The specification fails to provide any definitional guidance; what is “improved” to one person may not be to another.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mabie et al (USP 4,431,451).

The prior art discloses glazed crowns, inlays and dentures, wherein the glazing mixture has been “low-fired”. See the first paragraph of col. 6; see also col. 8, lines 31-45. Instant claim 19 merely requires “delivery” of a “composition” to the oral cavity. In the examiner’s opinion, where “composition” is interpreted as broadly as is reasonable in light of the teachings of the specification, that term is inclusive of the crown itself. Accordingly, claim 19 is viewed as being inclusive of the mere placement of a low-fired, glazed crown into the oral cavity for use as a dental implant. Furthermore, since a crown is a “composition to improve oral health” in a general sense (by ameliorating the effects of tooth decay), it also fairly anticipates claim 21 on that basis as well.

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2) Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayclin (USP 5,538,429).

The prior art disclose crowns which have been produced by roughening the crown surface, followed by curing ("low-firing") a polymeric coating (a "glaze") on said surface. See col. 2, lines 12-16 and 21-26. Accordingly, the prior art is viewed as anticipating the broadly claimed subject matter of the instant claims for the same reasons provided in subsection "1)" supra.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayclin (USP 5,538,429) in view of Rheinberger et al (USP 5,936,006).

The primary reference discloses crowns which have been produced by roughening the crown surface, followed by curing ("low-firing") a polymerizable coating composition (a "glaze") on said surface. See col. 2, lines 12-16 and 21-26. It differs from the instant claims insofar as it does not specifically disclose polymerizable coating materials containing an active ingredient such as an antimicrobial or flavoring agent; instead, it generally suggests the use of commercially available products (col. 2, lines 24 and 25).

The secondary reference teaches that polymerizable acrylate tooth coating (varnish) compositions (see the passage bridging the bottom of col. 2 and the top of col. 3) are ideally suited for use as coating agents (varnishes) for artificial tooth structures (see patent claim 2) because they provide, once cured ("low-fired"), improved mechanical properties and hardness (col. 6, lines 56-62). Furthermore, the prior art specifically teaches the incorporation of "conventional additives" such as antimicrobial and flavoring agents (col. 5, lines 17-22), therein. (The term "flavoring agent" is believed to fairly suggest, on its face, "flavoring oils" typically used in dental compositions as required by instant claim 22).

The secondary reference differs from the instant claims insofar as it does not specifically disclose, in the form of a preferred embodiment or a working example, a crown, inlay, onlay or veneer which has been glazed with the acrylate tooth coating

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composition. (It does mention such structures specifically at col. 4, lines 44-51, but in the context of adhesive bonding rather than coating).

It would have been obvious to have used an acrylate tooth coating composition (a "glaze") containing a flavoring agent or antimicrobial as the polymerizable coating composition of the primary reference, motivated by the desire to provide, upon curing ("low-firing") a coating having improved mechanical properties and hardness as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Fred', followed by a large, stylized circular flourish.